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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,623	08/19/2003	Janos Szamosi	AM100224 P1	4463

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,623	SZAMOSI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-39* is/are pending in the application.

4a) Of the above claim(s) *15-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 03/09/09 and the Supplemental Response filed 3/27/09 is acknowledged.

Applicant's traversal of the constructive election by the Examiner with regards to claims 38-39 is acknowledged. Applicant argues, "The claimed subject matter of claims 38 and 39 is an obvious variant of the use of the other claims as previously presented and is similar enough to the pending claims". Applicant's arguments have been considered and were found persuasive based on the amendment to the claims. Accordingly, previously withdrawn claims 38 and 39 have now been rejoined with the elected Group I invention (drawn to a tablet) (see Response to Restriction filed 11/09/06).

Claims 15-39 are pending in this action. Claims 32 and 36 have been amended. Claims 15-31 remain withdrawn (based on non-elected invention). Claims 38-39 have been rejoined with the elected invention (Group I). Claims 32-39 have been examined in this action. Claims 32-39 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 March 2009 has been entered.

* * * * *

Claim Objections

Claim 38 is objected to because of the following informalities: Claim 38 recites the term "a favor". The term contains a typographical error. The term "favor" should instead be recited as "flavor". Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 32 and 36 recite the limitation, "at least one non-saccharide excipient". A review of the instant specification establishes that the limitation "non-saccharide excipient" is not supported by the specification and thus, introduces new matter into the claims. The fact that all examples in the specification are drawn to non-saccharides (i.e., mono-, di- & polysaccharides) does not support the theory of excluding a specific category. Applicant has not provided support for the specific claim language of a "non-saccharide excipient" as is presently claimed. There is nothing in the specification to establish support for this concept.

* * * * *

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 34, 36 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 36 each recite the limitation, "at least one non-saccharide excipient". The claims are indefinite because while Applicants are claiming a "non-saccharide excipient", Applicants are also simultaneously claiming starches (i.e., cornstarch), as one of the non-saccharide excipients; starches are essentially sugars or saccharides. Starches are in essence, carbohydrates and carbohydrates in turn, are sugars (or saccharides). Starches are also considered polysaccharide carbohydrates. Thus, Applicant's limitation of a "non-saccharide excipient" is confusing since it is contradictory to what is being claimed (i.e., cornstarch is a polysaccharide). Applicant is claiming a "non-saccharide excipient" but also claiming a starch, which is a sugar (saccharide).

Claim 34 recites the limitation, "...wherein the low melting point compound is one or more compounds selected from the group consisting of hydrogenated oil and partially hydrogenated oil". The claim is indefinite because the limitation of "one or more compounds" is contradictory to what is being claimed in the original claim language (as in claim 32). The independent claim (claim 32), from which claim 34 depends, indicates "a low melting point compound", which is indicative of a *single*, not plural, low melting point compound. Thus, only

one low melting point compound can be present in the tablet. More than one low melting point compound is not permissible, given the original claim language.

Claim 34 recites the limitation "one or more compounds" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 (which depends from independent claim 38) recites the limitation, "...further consisting of a souring agent." The claim is indefinite because the "consisting of" language claimed in the original claim language (in independent claim 38) is closed-ended language which does not permit the presence of additional ingredients, such as the souring agent that is being claimed in claim 39. Thus, the claim is confusing in the sense that claim 38 is limiting in terms of its tablet ingredients, however, claim 39 aims to include additional ingredients, which is not permissible, given the original "consisting of" claim language of independent claim 38.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (U.S. Pat. No. 5,576,014) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

Mizumoto *et al.* ('014) teach an intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, such as corn starch, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

While Mizumoto *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Mizumoto *et al.* do not teach the selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglycercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Mizumoto *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglycerides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed

oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an effective drug delivery tablet.

* * * * *

Claims 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu *et al.* (U.S. Patent No. 6,299,904).

Shimizu *et al.* ('904) teach a solid preparation, which is a tablet, having fast disintegration that comprises (i) a pharmaceutically active ingredient; (ii) one or more water-soluble sugar alcohols selected from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol and (iii) low-substituted hydroxypropycellulose (see Abstract); (col. 1, lines 8-57); (Claims 1 & 6). Two or more water-soluble sugar alcohols can be used as a mixture in a given ratio (col. 4, line 66 – col. 5, line 2).

Lubricants are disclosed in the composition and include: sucrose fatty acid ester, polyethylene glycol, talc, stearic acid, etc. Polyethylene glycol can be used in an amount of 0.01 to 10 weight parts (col. 6, lines 26-34).

Additives are disclosed in the composition and include: artificial sweeteners such as aspartame, flavorants, lubricants, colorants, stabilizers, disintegrators, etc. (col. 5, line 59 – col. 6, line 25).

The tablets have a hardness of about 2 to about 20 kg (col. 8, lines 5-8). Applicant's recite a hardness of "less than about 2 kp", which nonetheless, would read on the "about 2 kp" taught by Shimizu.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Shimizu. Shimizu teaches a fast-disintegrating tablet comprising the same ingredients as claimed (drug, sugar alcohol/saccharide, polyethylene glycol (low melting point compound) whereby the tablets exhibit a suitable hardness. The reference teaches that their tablet exhibits excellent buccal disintegration and dissolution in combination with an appropriate strength or hardness and thus provides for ease of processing during manufacture.

* * * * *

Response to Arguments

Applicant's arguments filed 03/09/09 have been fully considered but were not found to be persuasive.

- **35 U.S.C. §103(a) rejection over Mizumoto et al. ('014) in view of Mauger et al. ('403):**

Applicant argued, "By amending to include 'consisting of' language, the current claim amendments unequivocally specify that the claimed compositions consist of a single saccharide. In contrast to Applicant's invention, Mizumoto neither suggests or teaches that a single saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities) or that a water soluble excipient in combination with a low melting point solid forms a fast dissolving granulation. Mizumoto stresses the importance of having both a low and high moldability saccharides present and teaches that they should be granulated together to get the best characteristics of each."

These arguments have been considered but were not deemed persuasive. It is agreed that Mizumoto permits the use of more than one saccharide. However, the claim language currently presented still permits the inclusion of additional agents asides from those instantly recited, including the more than one saccharide of Mizumoto. More specifically, the claims recite, in part, a "tablet consisting of a fast dissolve granulation, an active ingredient....wherein the fast dissolve granulation consists essentially of...". Thus, while the tablet feature itself utilizes closed-ended "consisting of" language, the fast-dissolve granulation feature utilizes "consisting essentially of" language which is not entirely closed-ended language. Hence, the fast-dissolve granulation would permit the additional saccharides disclosed by Mizumoto. It is the granule or granulation portion of Mizumoto that contains more than one saccharide, which is permissible given the instant claim language (which recites, "...fast dissolve granulation consists essentially of"). Thus, additional agents such as the additional saccharides of Mizumoto are not excluded by the "consisting essentially of" language of the fast-dissolve granulation feature. Furthermore, Applicant has not shown that the additional saccharide(s) taught by Mizumoto would be detrimental to the formulation, when present. Particularly in view of the fact that Applicants themselves demonstrate that the inclusion of two saccharides is permissible. Seven out of the eight examples disclosed by the Applicant utilize more than one saccharide. See for instance, Examples 1-7, all of which contain more than one saccharide. Thus, it cannot be seen as to how the additional saccharide of Mizumoto would be adversary to the formulation. Nonetheless, the "consisting essentially of" language does not preclude the additional saccharides of Mizumoto.

Applicant argued, "Mauger also does not disclose or suggest a combination including only a single saccharide. Mauger provides no teaching, suggestion or motivation to use a single saccharide even in the coating disclosed in Mauger much less any other capacity."

This argument was not found convincing. As delineated above, the fast-dissolve granulation feature of the tablet, which utilizes "consisting essentially of" language does not exclude or avoid additional agents, such as additional saccharides. Furthermore, the reference of Mauger is sufficient for all that it was relied upon. Mauger demonstrates the teaching that it is well known to one of ordinary skill in the art to incorporate monoglycerides, diglycerides and triglycerides derived from vegetable oils (i.e., palm kernel oil, cottonseed oils and the like), whereby the glycerides are effective for aiding in taste-masking of drugs and effective for enabling the composition to melt at body temperature. Thus, Mauger is ample for all that it suggests and teaches to one of ordinary skill in the art.

Accordingly, the 35 U.S.C. §103(a) rejection of claims 32-37 over Mizumoto *et al.* (USPN 5,576,014) in view of Mauger *et al.* (US 5,728,403) has been maintained.

- **35 U.S.C. §103(a) rejection over Shimizu *et al.* ('904):**

Applicant argued, "The hardness range claimed by Applicants is substantially lower than the range of 2-20 kg of Shimizu. None of the Shimizu examples have a hardness that comes closed to the recited lower boundary of 2 kg. Tablet hardness may impact a number of properties of a tablet, including processability, robustness and dissolution behavior."

This argument was not persuasive. The instant hardness of "about 1.7 kP" is not so far from and does not distinguish over the hardness range disclosed by Shimizu (2-20 kg), which

would also be considered a suitable hardness level. Applicant's argument that the "lowest hardness actually exemplified in Shimizu is 4.2 kg in Working Example 5" was not persuasive since the prior art is not limited to the specific working examples exemplified therein, but rather, the art is considered, as a whole, for what it teaches to one skilled in the art. Applicant's argument regarding properties affected by hardness was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., processability, robustness and dissolution behavior) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the prior art teaches a combination of the same elements provided in a similar fashion as that instantly claimed, and thus, it would be expected that the properties imparted by those elements would also be the same as that sought by Applicant.

Applicant argued, "Nowhere does Shimizu disclose or suggest the combination of a single saccharide and a low melting point compound to form a fast dissolving granulation comprising about 30% to about 75% of the tablet weight."

This argument was not deemed persuasive. Shimizu teaches a solid preparation – a tablet that has fast disintegration and that comprises a combination of an active ingredient, *one* or more water-soluble sugar alcohols (implying a single saccharide can be used) as well as ingredients such as polyethylene glycol. The polyethylene glycol disclosed would be a suitable low melting point compound. Regarding Applicant's argument that "Shimizu does not recognize the advantage of a low melting point compound", this was not convincing since "[T]he fact that

appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). With regards to the instant amounts of the fast dissolving granulation (about 30% to about 75% of the tablet weight), the Examiner points out that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The instant amounts claimed do not establish a patentable distinction over the explicit teachings of the art, which recognizes and teaches the same ingredients employed by Applicant.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

June 4, 2009